



UNITED STATES PATENT AND TRADEMARK OFFICE

Serial No. : 10/734,671  
Applicant : Foerster et al.  
Filed : 12/12/2003  
Group Art Unit: 3736  
Examiner : Apanius  
Docket No. : END-897DIV3  
Customer No.: 021884  
Title : METHODS AND DEVICES FOR DEFINING AND MARKING  
TISSUE

**APPEAL BRIEF**

Mail Stop Appeal Brief - Patents  
Commissioner of Patents and Trademarks  
PO Box 1450  
Alexandria, VA 22313-1450

Sir:

**REAL PARTY IN INTEREST**

Ethicon Endo-Surgery, Inc. is the real party in interest in the above referenced patent application.

## **RELATED APPEALS AND INTERFERENCES**

Neither Appellants' representative, Appellants' assignee, nor Appellants are aware of any appeals and/or interferences effected by or having a bearing on the Board's decision in the pending appeal.

## **STATUS OF CLAIMS**

Claim 49 is currently pending and stand finally rejected. Claims 1-48 have been canceled.

Appellants accordingly appeal the Examiner's Final Rejection of claim 49.

## **STATUS OF AMENDMENTS**

No amendments have been filed subsequent to the Final Rejection. As to the amendments filed prior to the Final Rejection, all amendments appear to have been entered and considered.

## **SUMMARY OF THE CLAIMED SUBJECT MATTER**

Claim 49 is the only independent claim involved in the present Appeal. As such, claim 49 is summarized below. Claim 49 sets forth a delivery system (10) for delivering marker material (12) to a target site (51) within a patient. The delivery system (10) includes an elongate member (54) having a distal end, a discharge port in the distal end and an inner lumen (56) extending therein to and in fluid communication with the discharge port in the distal end. A mass of solid particulate marker material (one or more 12i) is disposed within the inner lumen (56). The delivery system (10) also includes an ejector (18, 24) which is advancable with and coupled to said elongate member (54) and which is configured to eject particulate marker material from the discharge port in said distal end of said elongate member (54). Support is found throughout the Specification as originally filed where the reference numerals listed above are used.

## **GROUNDΣ OF REJECTION TO BE REVIEWED ON APPEAL**

1. Whether claim 49 is unpatentable under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement.
2. Whether claim 49 is unpatentable under 35 U.S.C. § 103(a) over U.S. Patent No. 3,741,198 to Burton (“Burton”) in view of U.S. Patent No. 5,123,414 to Unger (“Unger”).

## ARGUMENTS

### I. CLAIM 49 IS IMPROPERLY REJECTED UNDER 35 U.S.C. § 112, 1st paragraph.

Claim 49 stands rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The Specification as originally filed clearly discloses that the numerous different markers contemplated by the inventors are to be delivered via a tube 54 having a lumen 56, thus the written description inherently has to provide support for each and every marker 12a-j being “disposed within an inner lumen of the elongated member” as this is the only delivery means disclosed. Specifically, on numerous occasions in the Specification, the markers are disclosed as being preloaded, deployed or traveling through a lumen or tube. Page 7, lines 17-19, states, “[i]n some embodiments, these deployment functions are communicated by means of the marker elements themselves travelling through the lumen for deployment from the distal region”. Page 7, line 28, states, “...deployed from the lumen”. Page 8, line 4, states, “...deployment from the lumen...”. Page 15, lines 21-26, states, “[i]t is also within the scope of the invention to deliver the marker element through any tube which has access to the body or using optical medical instruments...through the body of the instrument”. Page 17, lines 9-11, states, “...a plurality of marker elements 12b (two are shown, though any number may be employed) may be preloaded into tube 54b...”.

Since the Examiner acknowledges that the disclosure supports a mass of solid particulate marker material, then it must also support delivering it via a tube and, in order to be delivered via the tube, the marker regardless of its form must at some point be disposed in the lumen in the tube.

One of ordinary skill in the art would surely be able to read the written description of the invention and then make and use what is claimed, which is all that 35 U.S.C. § 112, first paragraph requires. Therefore, the 112, 1<sup>st</sup> paragraph rejection is improper and should be reversed.

## II. CLAIM 49 IS PATENTABLE OVER BURTON IN VIEW OF UNGER.

Claim 49 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Burton in view of Unger. Appellants have claimed a delivery as described above in the "Summary" section.

Burton has been relied upon as teaching a syringe filled with a mass of solid particulate marker material disposed within an inner lumen. Although the Examiner asserts that "it is respectfully submitted that any material that can be detected in some manner can be considered a marker", it is Appellants' opinion Burton does not teach a marker material. A marker as claimed in accordance with the present invention has a specific purpose of marking a site and not traveling from that site. Contrary to what the Examiner believes, just because something is detectable does not in turn make it a marker.

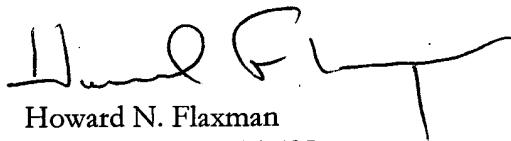
Appellant is delivering to a target site and not a moving site. If the marker were to move, it could no longer perform the function of marking the target site. Burton teaches a radiopaque contrast material in the form of a ferrofluid, which is a fluid containing magnetic particles for the purpose of moving the contrasting fluid up and down the spinal column. The ferrofluid may contain metallic particulate, but their purpose is not to mark. In fact, their purpose is to move the particles, and hence the fluid, along the spinal column during an examination. As such, Burton does not teach a marker and, in fact, teaches away from a marker. A marker as disclosed by Appellant is to mark a target site and Burton fails to teach marking a target site. With this in mind, Burton even if combined with Unger fails to teach the claimed invention.

Therefore, it is Appellants' opinion the rejection of claim 49 is improper and respectfully request the outstanding rejection be reversed.

## II. CONCLUSION

In conclusion, Appellants have now shown that the §112 rejection is improper and the references cited by the Examiner neither disclose nor suggest the claimed invention. Therefore, it is respectfully requested that the outstanding rejections of claim 49 be reversed.

Respectfully submitted,



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## **CLAIMS APPENDIX**

1-48. (Canceled)

49. A delivery system for delivering marker material to a target site within a patient, comprising:  
an elongate member having a distal end, a discharge port in the distal end and an inner  
lumen extending therein to and in fluid communication with the discharge port in the distal end;  
a mass of solid particulate marker material disposed within the inner lumen; and  
an ejector which is advancable with and coupled to said elongate member and which is  
configured to eject particulate marker material from the discharge port in said distal end of said  
elongate member.

## **EVIDENCE APPENDIX**

Not Applicable

**RELATED PROCEEDINGS APPENDIX**

Not Applicable